Exhibit 35-3

State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc. et al., Civil Action No. 03-11226-PBS

Exhibit to the November 25, 2009 Declaration of Philip D. Robben in Support of Defendants' Joint Motion for Partial Summary Judgment

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ARGUMENTS

Pro:

These amendments to the "express lane" statutory authority would allow this program to be implemented in accordance with federal law.

Con:

- County administrative funding has been cut by 20% in the Governor's proposed budget, thus creating further hardship on the counties with this workload increase.
- The July 1, 2003, implementation date may not be feasible, depending upon the budget situation for fiscal year 2003-04.

SECTION 44

ANALYSIS:

The amendments proposed to Welfare and Institutions Code, Section 14011, clarify the implementation date of accelerated enrollment (AE) for children to the date the SCHIP waiver is approved or July 1, 2002, whichever is later (program was implemented July 1, 2002). In addition, Subsection (h) has been added to require the counties to determine eligibility when they receive applications for children in the AE program. It also includes a requirement that the counties discontinue children from AE if found ineligible for Medi-Cal by entering minimum data elements into the Medi-Cal Eligibility Data System.

- Last year, AB 430 (Chapter 171, Statutes of 2001) added language to Section 14011 of the Welfare and Institutions Code to include the AE program for children. DHS has an approved state plan that designates a single point of entry to accept and screen applications of children for the AE program.
- This year, Section 44 of this bill would clarify the implementation date of AE to include the phrase "or on July 1, 2002, whichever is later" in Section 14011.6 (e).
- Section 14011.6 makes implementation of AE dependent upon federal approval of the state plan amendment (that currently has an effective date of July 1, 2002) and approval of the SCHIP waiver to expand Healthy Families to include parents. Both of these have been approved, however, the parental expansion has been delayed and, furthermore, the waiver has an expiration date. Either continued delay of implementation or expiration of the parental expansion waiver would leave DHS with unclear authority to continue the AE program for children. Some statutory provision should be made to de-link the program from the waiver.
- Section 44 would add Section 14011.6(h) of the Welfare and Institutions Code, containing operational instructions to counties upon receipt of an application for a child in the AE program. Those processes include entering minimum data elements into the Medi-Cal Eligibility Data System. Counties have been informed by All County Welfare Directors' Letters of the AE program

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and how to treat an application for a child in the AE program. Including such operational instructions in statute could allow DHS to make necessary systems changes without further amending statute.

LEGISLATIVE HISTORY:

AB 430 (Chapter 171, Statutes of 2001), added Section 14011.6 to the Welfare and Institutions Code, creating the AE program for children under Medi-Cal.

PROGRAM BACKGROUND:

The Medi-Cal program currently provides a safety net of full-scope health care benefits to approximately 6 million low-income individuals residing in California. Those individuals must meet certain restrictive income and resource criteria. They primarily consist of several groups; pregnant women; children under 21; individuals receiving California Work Opportunity and Responsibility to Kids and similarly situated families; and aged, blind and disabled individuals. The Medi-Cal program provides services at no cost to most participants. Some individuals, however, who have monthly income in excess of certain amounts based upon family size, must pay or incur certain amounts of health care expenses each month before Medi-Cal will pay for the remainder of their medical expenses for that month.

The Medi-Cal funding ratio is approximately 50/50 (state/federal). DHS is the single state agency charged under federal law with the administration of the program; however, the counties serve as agents of the State in determining the eligibility of the participants.

The federal Balanced Budget Act of 1997 created SCHIP through which participating states were provided the opportunity to design comprehensive coverage and health insurance for underinsured children. The act provided approximately \$24 billion in federal grant awards to provide insurance coverage over five years. States could expand their current Medicaid plans, develop a new program, or expand an existing program that provides health insurance, or use a combination of the two approaches. To obtain federal approval of the proposed Healthy Families parental expansion SCHIP waiver, statutes to implement AE were placed into the Welfare and Institutions Code, August 10, 2001.

OTHER STATES' INFORMATION:

Other states that have already implemented an AE or Presumptive Eligibility (PE) program for children into Medicaid are Connecticut, Nebraska, New Hampshire and New Mexico. Florida has enacted a program but has not yet implemented it. Massachusetts, New Jersey, and New York, have PE programs for both SCHIP and Medicaid.

FISCAL IMPACT:

For fiscal year 2001-02, the Legislature added \$4.809 million to provide AE on the basis of an income screen to children who apply through Single Point of Entry (SPE) for Medi-Cal and/or Healthy Families and who are screened eligible for no-cost Medi-Cat.

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Cost of services provided during the AE period is billed to Title XIX. The estimated cost to the Medi-Cal program for FY 2002-03, as reflected in the May 2002 estimate, is \$10,767,000 (\$5,383,500 GF). Section 44 would not result in any additional GF costs.

ECONOMIC IMPACT: None.

LEGAL IMPACT: Unknown.

APPOINTMENTS: None.

SUPPORT/OPPOSITION:

Support: None known. Opposition: None known.

ARGUMENTS:

Section 44 would facilitate implementation of AE, which would improve access to medical

coverage for a number of uninsured children in California while the counties make a full Medi-

Cal determination.

Would ensure that providers who treat these children can be paid by Medi-Cal.

Con: None

SECTIONS 45 & 46

ANALYSIS:

SEC. 45. Existing law authorizes the Medi-Cal program to provide medical services to certain lowincome, medically needy families. The Child Health and Disability Prevention (CHDP) program provides health assessments and immunizations to both Medi-Cal eligible children and children whose family incomes are too high for Medi-Cal but below 200% of the federal poverty level. The Healthy Families (HF) program provides comprehensive health, dental and vision services to uninsured children of working families with incomes below 250% of FPL. Among the provisions of this bill, in Sections 11-13, 18-24, and 46, are the requirements to use the CHDP program as a gateway to enrolling children in the Medi-Cal and HF programs. Section 45 requires DHS and MRMIB to seek federal approval for presumptive eligibility for children based on CHDP eligibility and to develop an electronic application to serve as an application for CHDP services and as an application for pre-enrollment in the Medi-Cal or HF programs. This section dictates a July 1, 2003 date for implementation for the electronic application and other provisions require the implementation of the pre-enrollment program no earlier than April 1, 2003. Since the program cannot be implemented until

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federal approval is received; the date for implementation of the electronic application should be 90 days following implementation of the program rather than a specific date, in case there is a delay in gaining federal approval.

SEC. 46. Section 1920 A of the federal Social Security Act allows states to submit a State Plan amendment which allows medical services to be provided to children under the age of 19 years during a presumptive eligibility period. Presumptive eligibility must be determined by a "qualified entity" defined by the state. This section of the bill authorizes DHS to seek such a State Plan Amendment and specifies the same requirements as stated in federal law. During the time the child is pre-enrolled (presumptively eligible) he/she will receive full-scope benefits and CHDP services until the last day of the month following the month of presumptive eligibility determination or until an application for Medi-Cal and HF is received and eligibility determined. The section also makes implementation subject to federal approval and the availability of federal financial participation.

PROGRAM BACKGROUND:

The CHDP program was implemented in 1973 to comply with federal Medicaid mandates for an Early and Periodic Screening, Diagnosis, and Treatment program for Medi-Cal eligible children and to assure that all low-income children in California have access to preventive health services and that federal financial participation is available. The program also provides State-funded health assessments and immunizations to approximately 1.1 million non-Medi-Cal-eligible children annually. Many of these children have never been assessed for Medi-Cal eligibility.

The HF program is authorized by the federal State Child Health Insurance Program (SCHIP), Title XXI of the Social Security Act, and was implemented in California in 1998. HF provides comprehensive medical, dental and vision services to uninsured children of working families with incomes of less than 250% of the federal poverty level. Approximately two-thirds of the cost of HF is contributed by federal Title XXI funds.

The Medi-Cal program was authorized in California in 1965, and provides medical services to certain needy and low-income residents who have no health insurance. Medi-Cal services are provided under authority of the federal Medicaid program, Title XIX of the Social Security Act, and federal funding covers about 50% of the cost of services. Section 1920 A of Title XIX and Section 2104(e)(1)(D) of Title XXI permits the states to adopt presumptive eligibility for children when a "qualified entity" enrolls the child based on preliminary information that family income does not exceed certain levels.

OTHER STATES' INFORMATION: Unknown.

FISCAL IMPACT:

Sec. 45. The annual cost of the CHDP Gateway program is estimated at \$390,340,000 TF (\$141,725,000 GF). This estimate includes \$60,043,000 TF (\$22,935,000 GF) in MRMIB costs.

Sec. 46. Fiscal impact is unknown.

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ECONOMIC IMPACT: Unknown.

LEGAL IMPACT: Not applicable.

APPOINTMENTS: None.

SUPPORT/OPPOSITION:

Support: None known.

Opposition: None known.

ARGUMENTS:

SEC. 45:

- Pros: Prevents elimination of the State-only CHDP program as proposed in the Governor's budget in January 2002.
- Is consistent with the Governor's April 3, 2002 press release describing support for a CHDP Gateway program to be used as an access point for Medi-Cal and Healthy Families programs.
- Expands comprehensive health care coverage to children from low-income families.
- Permits a more efficient enrollment process for children to access medical services.
- Promotes access to federal funds for covering medical services to children.

Cons:

- Initial cost for developing program
- Initial cost for developing electronic application.
- Ongoing costs for expanded access to full-scope Medi-Cal or HF benefits.

SEC. 46:

Pros:

- Prevents elimination of the State-only CHDP program as proposed in the Governor's budget in January 2002.
- The pre-enrollment provisions (such as period of coverage) are consistent with federal presumptive eligibility requirements.
- Expands comprehensive health care coverage to children from low-income families
- Permits a more efficient enrollment process for children to access medical services.
- Promotes access to federal funds for covering medical services to children while a child is applying for the Medi-Cal or Healthy Families programs.

Const.

- Initial cost for developing program
- Initial cost for developing electronic application.
- Ongoing costs for expanded access to full-scope Medi-Cal or HF benefits.

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SECTION 47

ANALYSIS:

As a result of the approval by the Centers for Medicaid and Medicare Services (CMS) of the California State Children's Health Insurance Program (SCHIP) Demonstration Project, DHS began the process of developing a tracking and monitoring system for all Medi-Cal applications sent to the counties by the SPE. Because not all counties have an interface between automated systems and MEDS, a system to input the information manually was developed. This proved to be a workload issue for the CWDs. Section 47 was proposed by the CWDA to require the minimum amount of manual tracking by the CWDs necessary to ensure that Medi-Cal benefits are not continued for accelerated children subsequently found to be ineligible.

The Governor's May 15, 2002 budget revision provided \$11,000,000 to cover county costs of manually reporting to MEDS the status of all Medi-Cal applications processed through the SPE, including those applications from families who were not eligible for AE.

The CWDA has requested that the State delay this requirement until such time that the counties are able to electronically interface with MEDS. Instead, CWDA requests that the requirement to manually report application status be limited to the denial of AE applications. This requirement is recognized as the minimum reporting necessary in order to assure that Medi-Cal benefits will not be continued indefinitely for AE children found to be ineligible to the program.

The Special Terms and Conditions of the SCHIP 1115 waiver, approved by CMS in January 2002, includes requirements for DHS and MRMIB to track and report the status of applications forwarded from the SPE to the counties and vice versa, in an effort to quantify the results of the coordination efforts between the two programs. One of those requirements is the tracking of Medi-Cal applications denied by the counties.

However, while the Special Terms and Conditions of the SCHIP 1115 waiver requires DHS to report Medi-Cal denials and certain reasons for those denials, the provisions of that waiver also give the State the flexibility to limit the reporting to those counties with the capability to do so. Currently, only the Los Angeles LEADER system is able to establish an interface with MEDS, which enables the county to record and report such information. Because of this exemption, DHS would not be out of compliance with the Terms and Conditions of the waiver if this section of the Health Trailer Bill were implemented.

Section 47 of the Health Trailer Bill provides legislative intent for the automated systems to be in place by July 1, 2003. However, DHS is concerned that it does not provide a deadline for all counties to begin the comprehensive tracking of all applications as originally proposed by the Administration.

LEGISLATIVE HISTORY: None.

PROGRAM BACKGROUND:

Joint applications for Medi-Cal and Healthy Families are sent to a central processing unit, the Single Point of Entry (SPE). The applications are screened and then forwarded to either the HFP or the

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CWD in which the applicant lives. It is anticipated that the majority of applications received from SPE will be eligible for AE. These cases will be approved for AE and will remain approved until the CWD reports a denial or approval for Medi-Cal. If the CWD does not report an approval or denial, the individual will remain in AE indefinitely.

OTHER STATES' INFORMATION: None known.

FISCAL IMPACT:

The California Welfare Directors Association estimates the cost of the tracking of AE denials under this section to be \$3,000,000.

ECONOMIC IMPACT: None.

LEGAL IMPACT: None.

APPOINTMENTS: None.

SUPPORT/OPPOSITION:

Support: CWDA

Opposition: None known.

ARGUMENTS:

Pros: This bill would allow CWDs time to develop the necessary interfaces between their automated systems and MEDS without a workload increase. This bill would result in a total fund cost of \$3,000,000 for only tracking denied AE applications, until all counties have the ability to interface with MEDS.

Cons: This bill would delay the collection and dissemination of data necessary to increase coordination efforts between the Medi-Cal and Healthy Families Programs.

SECTION 47.5

ANALYSIS:

This section would, to the extent permitted by federal law, allow DHS to waive overpayments made to a pharmacy provider that would otherwise be reimbursable to DHS for prescription drugs returned to the pharmacy provider from a nursing facility upon discontinuation of the drug therapy or the death of the beneficiary.

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When a drug is dispensed to a patient in a nursing facility, it is packaged in what is commonly referred to as a "bubble" pack. Each bubble contains a tablet or capsule. The bubble is hermetically sealed. Since the bubble is sealed, pharmacy law allows unused doses to be returned to the dispensing pharmacy's stock. When returning drugs to stock, the pharmacy is required to store the returned drugs in a container labeled with a specific lot number and expiration date.

Currently, pharmacy providers must reimburse Medi-Cal for the drugs, paid for by Medi-Cal, that have been returned to stock. In doing so, pharmacy providers contend that they lose money due to the labor costs associated with restocking the drug. Therefore, most, if not all, long-term care pharmacy providers opt to destroy unused drugs instead. There is no requirement that they restock the unused medication.

Long-term care pharmacies also appear to have higher costs of dispensing drugs than other pharmacies, due to the various requirements placed upon them by state and federal laws and regulations. These providers contend that the reimbursement reduction proposed in SEC. 73 of this bill would make it financially impossible to continue to provide services to Medi-Cal beneficiaries.

This section would give financial relief to these pharmacy providers without affecting proposed savings in the budget.

LEGISLATIVE HISTORY:

This fiscal approach has never been proposed legislatively.

PROGRAM BACKGROUND:

The Medi-Cal drug program in DHS maintains the outpatient drug List. This List is used by physicians when prescribing medications for FFS Medi-Cal patients. Drugs not specifically listed remain a Medi-Cal benefit subject to prior authorization from a Medi-Cal consultant. State legislation was enacted in 1990 that enabled DHS to contract with drug manufacturers to obtain rebates for drugs dispensed to FFS outpatient Medi-Cal beneficiaries. This rebate program complements, rather than conflicts with the federal Medicaid rebate law. Because of negotiating state supplemental rebates, DHS often secures rebates in addition to those required under federal law. Rebates over and above those required to be paid to the State under federal law have been possible due to leverage DHS has with manufacturers regarding drug contracting in exchange for adding their drugs to the List.

OTHER STATES' INFORMATION:

Minnesota requires that medications dispensed in unit-dose packaging be returned to the pharmacy and credited to Medicaid. However, this only applies if the packaging meets standards established by the Minnesota Board of Pharmacy.

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From Minnesota statute:

"An additional dispensing fee of \$.30 may be added to the dispensing fee paid to pharmacists for legend drug prescriptions dispensed to residents of long-term care facilities when a unit dose blister card system, approved by the department, is used. Under this type of dispensing system, the pharmacist must dispense a 30-day supply of drug. The National Drug Code (NDC) from the drug container used to fill the blister card must be identified on the claim to the department. The unit dose blister card containing the drug must meet the packaging standards set forth in Minnesota Rules, part 6800.2700, that govern the return of unused drugs to the pharmacy for reuse. The pharmacy provider will be required to credit the department for the actual acquisition cost of all unused drugs that are eligible for reuse."

FISCAL IMPACT:

There is no fiscal impact since there is no increase or decrease of expenditures related to this section. Long-term care pharmacies are currently destroying unused drugs. The Medi-Cal program is currently reimbursing for each prescription provided to a Medi-Cal eligible long-term care resident.

ECONOMIC IMPACT:

There would be a positive economic impact on long-term care pharmacies that, according to the providers, will enable them to continue providing services Medi-Cal beneficiaries.

LEGAL IMPACT: Unknown.

APPOINTMENTS: None.

SUPPORT/OPPOSITION:

Support: None known. Opposition: None known.

ARGUMENTS:

Pros: Would help ensure access to pharmacy services for Medi-Cal beneficiaries residing in nursing

facilities.

Cons: None

SECTION 48

Federal law provides that children covered under the federal, or Title IV-E of the Social Security Act, Adoption Assistance Program (AAP) are eligible to receive Medicaid from the state of residence even if that state is not the state that entered into the adoption agreement. There is no corresponding law. for non-federal, state-only AAP agreements. When a child is receiving state-only AAP from a state other than their state of residence, the child may not be able to access Medicaid services in their state of residence.

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Existing State law (SB 1270, Chapter 887, Statutes of 1999) provides that a child is eligible to receive Medi-Cal benefits pursuant to interstate agreements for adoption assistance and related services and benefits, regardless of which state is providing the AAP payments. Without the language in Section 48, this provision becomes inoperative on October 1, 2002, thus eliminating the assurance of Medi-Cal eligibility for these children.

To make adoption of special needs children truly workable, the adoptive parents must be assured that they will actually receive the promised AAP payments and Medicaid benefits regardless of where within the United States they reside. Children in the AAP are children who were in the foster care system and who were considered difficult to adopt. Typically, they suffer serious health, emotional and developmental problems, and are reliant on government-funded health services to respond to their complicated health conditions.

If the existing state law were to sunset, the situation would revert to the way it was prior to 1999. When a child was receiving state-only AAP from California, the child was eligible for Medi-Cal and could keep Medi-Cal when relocating to another state. Once resettled out of state, the child had to find a provider in the new state who will accept Medi-Cal. In many instances, the child was unable to find a Medi-Cal provider or was unable to be covered for the full range of Medi-Cal services.

This put an undue financial burden on the adoptive parents. As an alternative, some families applied for the receiving state's Medicaid program. This, however, required that the income and resources of the adoptive parents be considered in the Medicaid determination. A state-only AAP child entering California with an AAP agreement from another state faced the same difficulties.

Children who lose Medi-Cal coverage under this program would have to revert to the sending state's Medicaid program and then hopefully find a provider in California who would take the out-of-state Medicaid. In order for the child to qualify for Medi-Cal, the family must meet deprivation, resources, etc., requirements.

Also included in SB 1270 was language providing that Medi-Cal coverage for state-only AAP children would become ineffective (sunset) on October 1, 2002. It was upon the federal sunset date that the State's sunset date was established. While the incentive payments will sunset in federal law, DHS recommends continuation of this program so as to not take away coverage to pre-existing children in the program who have special needs and due to the relatively small cost of continuing this program.

Providing Medi-Cal benefits to children entering the State not only improves the chances of finding adoptive families for waiting special needs children, it improves the chances of successful adoptions across state lines. This is true whether the child is receiving adoption assistance through the federal adoption assistance program or the state adoption assistance program. It is to the State's advantage to provide these benefits because if the adoption disrupts, and the child ends up in foster care placement, California must then bear the financial burden of the child, not the adoption assistance state.

LEGISLATIVE HISTORY:

On November 13, 1997, the President signed the Adoption and Safe Families Act of 1997 (Public Law 105-089) into law. Section 473A of Title IV-E of the Social Security Act provided for a grant program to provide incentives for states to seek additional foster care adoptions. In response to this legislation, Senate Bill 1270 (Aroner, Chapter 887, Statutes of 1999) was developed and implemented in order to provide incentive payments to the Department of Social Services of \$4,000 for each FC adoptions for fiscal year 2001 and 2002. The federal incentive program ends October 1, 2002. The legislation required a change to the Medi-Cal program that would allow AAP children who are the subject of an AAP agreement with any state and receiving state-only AAP funds to be eligible for Medi-Cal. The legislation also provided authority for California" joinder in the Interstate Compact on Adoption and Medical Assistance (ICAMA). Membership in ICAMA provides a binding agreement among party states to administer the delivery of interstate benefits and services, including Medicaid, for AAP children. California's membership in ICAMA will be in jeopardy if legislation is not enacted to extend or eliminate the sunset of the AAP Medi-Cal authorization.

PROGRAM BACKGROUND:

The Medi-Cal program provides health care services to low-income individuals who meet the program's eligibility requirements. Children in the California foster care system and children adopted pursuant to an Adoption Assistance Program agreement in California are automatically eligible for the Medi-Cal program.

OTHER STATES' INFORMATION:

As of June 2002, 39 states provide Medicaid to AAP children residing in their state who are receiving state-funded adoption assistance from another state. Six states are in the process of initiating programs to provide Medicaid to these children. This leaves five states that do not provide Medicaid benefits to children who have adoption assistance from another state.

FISCAL IMPACT:

G.F. Other	Current FY \$19,000 \$19,000	Budget FY \$19,000 \$19,000 \$38,000 N/A	Annual Ongoing FY \$19,000 \$19,000 \$38,000 N/A
Total PYs	\$38,000 N/A		

The elimination of the sunset for this program would not result in any new costs to the Medi-Cal program. There are currently 28 children utilizing this program. The continued cost of this program is offset by savings for children from California who are placed out-of-state that no longer need Medi-Cal coverage. Savings are indeterminate, but estimated to be equal or greater than the cost of covering children placed in California.

Providing Medi-Cal benefits to children entering the State not only improves the chances of finding adoptive families for waiting special needs children, it improves the chances of successful adoptions across state lines. This is true whether the child is receiving adoption assistance through the federal adoption assistance program or the state adoption assistance program. It is to the State's advantage to provide these benefits because if the adoption disrupts, and the child ends up in foster care placement, California must then bear the financial burden of the child, not the adoption assistance state.

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ECONOMIC IMPACT: Unknown.

LEGAL IMPACT: Unknown.

APPOINTMENTS: None.

SUPPORT/OPPOSITION:

Support: None known. Opposition: None known.

ARGUMENTS:

Pro:

- Provides AAP children with necessary health coverage and appropriate heath care when relocating in California without putting an undue hardship on the adoptive parents and without interrupting the treatment an AAP child may be receiving.
- Joinder with ICAMA has provided the states and AAP children involved in an out-of-state move with a more streamlined process with common transfer forms and contact persons from other states as well as enforcement of the Compact. Without legislation to extend the AAP Medi-Cal authorization, California's membership will be in jeopardy. If California loses membership it will be harder to place California foster children in homes out of state if the families move.

Con:

Potential for increased cost to the Medi-Cal program, to the extent that more children become eligible.

SECTION 49 & 50

Currently, DHS may accept funds for deposit into the GME I and GME II Funds. The transferring entity must certify that the funds qualify for federal financial participation. These sections would extend the sunset on these programs for two years, until July 1, 2004, thus continuing a source of federal funding for a portion of the teaching costs associated with hospitals that serve Medi-Cal beneficiaries.

Payments from the funds are at the discretion of the California Medical Assistance Commission (CMAC), and are negotiated between the commission and SPCP contracting hospitals that are defined as either UC teaching hospitals; major (non-university) teaching hospitals; large teachingemphasis hospitals that are disproportionate share hospitals, or children's hospitals that are disproportionate share hospitals. Chapter 294, Statutes of 1997 (SB 391), created two funds for teaching hospitals. These two funds are entitled the Medi-Cal Medical Education Supplemental Payment Fund, also referred to as the General Medical Education (GME I) Fund, and the Large Teaching Emphasis and Children's Hospital Medi-Cal Medical Education Supplemental Payment Fund, also referred to as the General Medical Education (GME II) Fund.

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LEGISLATIVE HISTORY:

SB 391, Chapter 294, Statutes of 1997, was enacted to add sections 14085.7 and 14085.8 to the W&I Code, which created the Medi-Cal Medical Education Supplemental Payment Fund, and the

Large Teaching Emphasis Hospital and Children's Hospital Medi-Cal Medical Education Supplemental Payment Fund, respectively. W&I Code Sections 14085.7 and 14085.8 provide funding for a portion of teaching costs associated with hospitals that serve Medicaid beneficiaries through the SPCP.

AB 2877 (Chapter 52, Statutes of 2000) extended the sunset date to July 1, 2002 and the repeal date to January 1, 2003. This legislation was intended to be a stopgap measure until the teaching hospitals could come up with another funding source. A UC report to address the funding issues was submitted to CMAC, but the recommendations are the status quo with the state and federal governments sharing in the funding.

PROGRAM BACKGROUND:

The Medi-Cal Operations Division is responsible for ensuring that appropriate medical services are accessible and available to Medi-Cal beneficiaries and are provided in the most cost-effective manner. This is accomplished, in part, by selectively contracting with hospitals to provide acute inpatient care to Medi-Cal beneficiaries at rates negotiated by CMAC.

OTHER STATES' INFORMATION: Unknown.

FISCAL IMPACT:

This section would not result in any increased cost to the Medi-Cal program, as Fiscal Forecasting has budgeted funds for these two supplemental payment programs to continue.

ECONOMIC IMPACT: Unknown

LEGAL IMPACT: Unknown

APPOINTMENTS: None.

SUPPORT/OPPOSITION:

Opposition: None known. None known. Support:

ARGUMENTS:

Pros:

Would not result in any General Fund expenditures.

- Will provide continued funding for medical education in teaching hospitals.
- CMAC will continue to have the discretion to negotiate with contract hospitals that qualify under the provisions of the two funds.

Cons: None.

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SECTION 51 & 52

In Fiscal Year (FY) 2000-01, DHS submitted a Budget Change Proposal to hire additional pharmacy staff due to the increase in drug Treatment Authorization Requests (TARs). DHS subsequently received approval to hire up to 58 Pharmaceutical Consultants through Medi-Cal's fiscal intermediary. However, in FY 2001-02, DHS submitted another BCP for additional nurses due to an increase in overall TAR workload. Since DHS had only hired 30 of the authorized 58 positions previously approved, the Department of Finance recommended that the authority for the remaining 28 contract positions be used to hire contract staff as Nurse Evaluators in lieu of the request for additional state staff. The current statute related to contracting for TAR processing only allows DHS to contract for pharmacy consultant staff to process a specific type of drug TAR. Sections 51 and 52 would provide DHS with statutory authority to contract for staff to perform TAR and case management activities.

LEGISLATIVE HISTORY:

AB 2877 (Chapter 147, Statutes of 1994) amended the Welfare and Institutions Code Section 14133.22 to allow DHS to contract either directly, or through the fiscal intermediary, for pharmacy consultant staff to process certain drug TARs.

PROGRAM BACKGROUND:

DHS's Medi-Cal Operations Division (MCOD) is responsible for the authorization of a broad scope of medically necessary services provided to California's Medi-Cal Fee-For-Service (FFS) beneficiaries through utilization review and control measures. With oversight from six Medi-Cal Field Offices and two Pharmacy Sections, MCOD ensures timely access to high quality health care services. MCOD staff foster positive relationships between Medi-Cal beneficiaries and providers through their direct involvement with the provider community. MCOD staff is also responsible for ensuring that Medi-Cal beneficiaries are afforded access to health care services.

Specific medical services are subject to prior approval from MCOD. Providers submit TARs for services to the Field Offices for approval. MCOD Field Offices have a statutory mandate [Welfare and Institutions (W&I) Code, Section 14133.9(d)] to approve, modify, defer, or deny the requested service within an average of five working days of receipt.

As an extension of the TAR processing function, in 1992, MCOD began case managing chronic and/or catastrophic fee-for-service Medi-Cal beneficiaries.

Medi-Cal providers have the regulatory right to a first- and second-level appeal of any TAR that is modified or denied.

OTHER STATES' INFORMATION: None.

FISCAL IMPACT:

These sections would have no fiscal impact, as the 28 positions to be filled with nurse evaluators were already included in the budget as pharmacy consultants.

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ECONOMIC IMPACT: Unknown.

LEGAL IMPACT: Unknown.

APPOINTMENTS: None.

SUPPORT/OPPOSITION:

Support: None known.

Opposition: The American Federation of State, County and Municipal Employees (AFSCME) Local

2620, and the California State Employees Association.

ARGUMENTS:

Pros:

- Allows DHS to utilize existing contract and position authority to meet workload demands.
- In the event of workload reductions, the proposed legislative change would afford DHS greater flexibility to avoid potential state employee layoffs by hiring contract staff instead of permanent state employees.

Cons:

Because the proposed legislative change would allow contract staff to perform the same work currently performed by state employees, the California State Employees Association (CSEA), and the American Federation of State, County and Municipal Employees (AFSCME) Local 2620 have been resistant to this legislation.

SECTION 53

ANALYSIS:

Electronic Data Systems (EDS) manages the payment processing system for the following programs: the California Children's Services Program, the Genetically Handicapped Person's Program, the Breast and Cervical Cancer Early Detection Program, the State-Only Family Planning Program, and the Family PACT Waiver Program. EDS, the current fiscal intermediary for DHS, has maintained the same reimbursement rate methodology for these programs and procedures as those in the Medi-Cal program. Section 53 would help keep that uniform system: if Medi-Cal rates for certain procedures are reduced by 5%, then rates for any similar procedures in any of the five programs would also be reduced by 5%. The same process would apply if rates were to be increased. Thus, Section 53 would require provider rates of payment for services rendered in all of these five programs be identical to rates of payment for the same service performed by the same provider type pursuant to the Medi-Cal program. Reimbursement rates for any procedures in these five programs would be tied to similar reimbursement rates for corresponding procedures in the Medi-Cal program.

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Enrolled Bill Report Page 69 Bill Number: AB 442
Author: Committee on Budget

LEGISLATIVE HISTORY: None.

PROGRAM BACKGROUND: None.

OTHER STATES' INFORMATION: Unknown.

FISCAL IMPACT:

This language would help control the expenditures of the five programs, by tying their rates to changes in Medi-Cal provider rates.

ECONOMIC IMPACT: None.

LEGAL IMPACT: Unknown.

APPOINTMENTS: None.

SUPPORT/OPPOSITION:

Support: None known. Opposition: None known.

ARGUMENTS:

Pro: Section 53 provides some consistency: One single procedure code (therefore payment

methodology) will be adopted and kept for similar procedures, whether they are from the Medi-

Cal program or from any of the five programs affected by Section 53.

Cons: None

SECTION 53.5

ANALYSIS:

This section would reduce the reimbursement for medical supplies in Medi-Cal from a 25 percent markup on the acquisition cost to a 23 percent markup. This section also changes the reimbursement of diabetic testing supplies from a 25 percent markup to a dispensing fee equal to the dispensing fee for prescription drugs.

Providers of medical supplies recommended this language as an alternative to significantly reducing reimbursement on incontinence medical supplies. Providers contend that they are better able to absorb broad-based reductions than reductions focused on one product category. Annual expenditures for medical supplies, excluding incontinence supplies (see SEC. 81 analysis), equal approximately \$68.5 million Total Funds (TF) and for diabetic testing supplies equal approximately \$65.6 million TF.

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Enrolled Bill Report Page 70 Bill Number: AB 442

Author: Committee on Budget

LEGISLATIVE HISTORY:

Medical supplies were added as a benefit of the Medi-Cal program in 1976. Federal Medicaid law classifies medical supplies as an optional benefit. California Code of Regulations, Title 22, §51320 lists medical supplies as a benefit when prescribed by a physician. California law lists medical supplies as a benefit in the Welfare and Institutions Code §14132(m).

PROGRAM BACKGROUND:

The Medi-Cal drug program in DHS maintains the list of medical supplies required under federal law. Medical supplies on the list are benefits of the Medi-Cal program when prescribed by a physician (whether or not the item requires a prescription under law).

OTHER STATES' INFORMATION: None available

FISCAL IMPACT:

The change from a 25 percent to a 23 percent markup will save approximately \$1.278 million TF (\$0.639 million GF). The change from a 25 percent markup to a flat dispensing fee of \$4.05 per claim will generate savings of \$9.7 million TF (\$4.85 million GF).

ECONOMIC IMPACT:

There would be a negative economic impact on providers of medical and diabetic testing supplies, however these providers say that they would be able to absorb these reductions.

LEGAL IMPACT: Unknown.

APPOINTMENTS: None.

SUPPORT/OPPOSITION:

Support: None known.

Opposition: Independent Pharmacy Coalition

ARGUMENTS:

Pros: Would help reach projected budget reductions without serious economic impact on providers or significant reductions in beneficiary access.

Cons: Some providers may opt out of the Medi-Cal program due to the reduction in reimbursement, regardless of the extent of the economic impact.

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Author: Committee on Budget

SECTION 54

ANALYSIS:

This section would restrict DHS contracting with clinical laboratories to only those laboratories that operate under specific provisions of state and federal law. DHS already has general statutory authority to contract with clinical laboratories. It would also ensure Medi-Cal beneficiary access to high quality laboratory services. Additionally, this section would allow DHS to contract with its FI for consultant pharmacist staff needed for drug rebate contracting.

DHS plans to begin contracting on a bid or negotiated basis with laboratories for clinical laboratory services covered under the Medi-Cal program. In doing so, DHS projects that it will be able to reduce expenditures for clinical laboratory services. For clinical labs, using the Month of Payment method, which excludes Family PACT (aid code 8H) beneficiaries, Medi-Cal lab service expenditures in 2001 were \$95.7 million. This section would ensure that the contracts would be executed with only those laboratories that are operating according to law (Chapter 3 (commencing with §1200) of Division 2 of the Business and Professions Code and the regulations adopted thereunder, and §263a of Title 42 of the United States Code and the regulations adopted thereunder). It would ensure adequate access for Medi-Cal beneficiaries to quality laboratory testing services. It also requires DHS to consult with clinical laboratories and other stakeholders on contract provisions to ensure beneficiary access.

This section also gives DHS the authority to obtain pharmacist staff through the FL. Additional staff is needed for the increased supplemental rebate contracting activities targeted to reduce expenditures in the Medi-Cal drug program. The marketplace for pharmacists is highly competitive and this would give DHS the "hiring option" it may need if unable to hire pharmacists into existing or recently created state positions. The wages of state pharmacists are currently 40 percent less than the community standard.

LEGISLATIVE HISTORY:

The Medi-Cal program covers laboratory services in accordance with Title 22, California Code of Regulations, §51311. Budget Trailer Bill, Chapter 69, Statutes of 1993, amended Welfare and Institutions (W&I) Code §14105.3(b) to require DHS to enter into exclusive or nonexclusive contracts on a bid or negotiated basis with laboratories for clinical laboratory services for the purpose of obtaining the most favorable prices to the state and to assure adequate quality of the product or service. This negotiation process was never implemented for lack of additional staff needed by DHS.

Prior to 1990, DHS did not contract for supplemental drug rebates. Budget Trailer language established the original contracting authority in 1990. Chapter 716, Statutes of 1992 (SB 1063) extended a January 1, 1993, sunset date to January 1, 1999; Chapter 722, Statutes of 1992 (SB 485) revised the sunset date back to January 1, 1997. Chapter 197, Statutes of 1996 (AB 3483) extended the sunset date to January 1, 1999. Chapter 310, Statutes of 1998 (AB 2780) extended the sunset date to January 1, 2000. Chapter 146, Statutes of 1999 (AB 1107) extended the sunset date to January 1, 2001. Chapter 93, Statutes of 2000 (AB 2877) extended the sunset date to January 1, 2003.

Author: Committee on Budget

PROGRAM BACKGROUND:

The Medi-Cal Policy Division is responsible for administering the policy development, interpretation and implementation of the State's Medicaid program. The Benefits Branch is responsible for establishing the scope of benefits, conditions of coverage and utilization controls. This policy is consistent with the Administration's goal of making health care more readily accessible to children and adults. DHS already has the authority (W&I Code §14105.3(b)) to negotiate contracts with manufacturers of Durable Medical Equipment (DME) as well as medical supplies and other producttype health care services, and for clinical laboratory services.

The Medi-Cal drug program in DHS maintains the outpatient drug List. This List is used by physicians when prescribing medications for FFS Medi-Cal patients. Drugs not specifically listed remain a Medi-Cal benefit subject to prior authorization from a Medi-Cal consultant. State legislation was enacted in 1990, that enabled DHS to contract with drug manufacturers to obtain rebates for drugs dispensed to FFS outpatient Medi-Cal beneficiaries. This rebate program complements, rather than conflicts with the federal Medicaid rebate law. Because of negotiating state supplemental drug rebates, DHS often secures rebates in addition to those required under federal law. Rebates over and above those required to be paid to the State under federal law have been possible due to leverage DHS has with manufacturers regarding drug contracting in exchange for adding their drugs to the List.

OTHER STATES' INFORMATION: None

FISCAL IMPACT:

For clinical labs, using the Month of Payment method, which excludes Family PACT (aid code 8H) beneficiaries, Medi-Cal lab service expenditures in 2001 were \$95.7 million. If contracting for clinical laboratory services was established, DHS estimates savings of approximately \$5.615 million TF (\$2.8075 million GF).

Additional full-time staff (5 PYs) would be needed to implement and oversee the clinical laboratory services contracting program and the DME Contracting program. Staff will need to establish standards for clinical laboratory tests subject to contracting, initiate bids as necessary, write regulations if needed, develop clinical laboratory distribution and access networks and monitor contract compliance.

ECONOMIC IMPACT:

If DHS contracts with less than all laboratories currently providing services for Medi-Cal beneficiaries, some laboratories would lose revenue. The significance of the potential revenue loss is unknown.

LEGAL IMPACT: Unknown.

APPOINTMENTS: None.

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Author: Committee on Budget

SUPPORT/OPPOSITION:

Support: None known. Opposition: None known.

ARGUMENTS:

Pro: Would help reach projected budget reductions without while ensuring beneficiary access to

quality laboratory services.

Con: None

SECTIONS 55 & 56

ANALYSIS:

These sections would eliminate the January 1, 2003, sunset provisions of the Medi-Cal drug rebate program (SEC. 55,56,59,60,62,63,65,66,68,69) and would delete sections of law that become operative due to the January 1, 2003, sunset (SEC. 64,67,75,78,79,80). Several sections contain clean-up language changing Health Care Financing Administration to its new title, Centers for Medicare and Medicaid Services (SEC. 56,59,70).

Budget Trailer Bill language established the Medi-Cal drug rebate program in 1990. Since that time several extensions to the sunset date have been enacted. The most recent extension of the Medi-Cal drug rebate program was enacted in AB 2877 (Chapter 93, Statutes of 2000) for two additional years and is now due to sunset January 1, 2003.

Eliminating the sunset date and related sections would enable DHS to continue to operate the drug rebate program as it has since 1990. The sunset of the Medi-Cal drug rebate program would cause the:

- DHS to lose authority to collect \$280 million in rebates greater than the federally-mandated amount;
- Program to revert to a lengthy and burdensome regulatory process for making changes to the Medi-Cal drug formulary.

The elimination of the sunset is consistent with the following provisions of DHS's Strategic Plan: 1) Ensuring fiscal accountability of programs and services; 2) Reforming DHS's administration and program management, including external contracting, into a rational, business-like, and outcome oriented approach.

The Medi-Cal drug rebate program currently generates significant fiscal savings per year in rebates over-and-above the rebates paid to the State under the federal Medicaid drug rebate program. Reauthorization of this program would avoid the loss of these additional drug rebate savings. Without reauthorization, beginning January 1, 2003, current law requires DHS to return to the system in place prior to 1990 in which there was no drug contracting for additional rebates and each addition to the drug formulary required a change in regulations. Neither DHS nor drug manufacturers would like to

Author: Committee on Budget

reinstate the regulatory process as a requirement for drug additions to the Medi-Cal drug formulary. Drug additions through this regulatory process were much slower compared to the current contract negotiation process (18 months average compared to 6 to 9 months). This now obsolete process also resulted in fewer new drug additions (4 to 5 new drug additions per year in 1988 and 1989 compared to 20 to 30 new additions per year from 1996 to 1998), presumably due to cost concerns that are often mitigated through drug rebate contracting.

LEGISLATIVE HISTORY:

Prior to 1990, DHS did not contract for supplemental rebates and each addition to the Medi-Cal drug formulary required a change in regulations. Budget Trailer Bill language established the original contracting authority in 1990. Chapter 716, Statutes of 1992 (SB 1063) extended a January 1, 1993, sunset date to January 1, 1999; Chapter 722, Statutes of 1992 (SB 485) revised the sunset date back to January 1, 1997. Chapter 197, Statutes of 1996 (AB 3483) extended the sunset date to January 1, 1999. Chapter 310, Statutes of 1998 (AB 2780) extended the sunset date to January 1, 2000. Chapter 146, Statutes of 1999 (AB 1107) extended the sunset date to January 1, 2001. Chapter 93, Statutes of 2000 (AB 2877) extended the sunset date to January 1, 2003.

PROGRAM BACKGROUND:

The Medi-Cal drug program in DHS maintains the Medi-Cal List of Contract Drugs (List). This outpatient drug List is used by physicians when prescribing medications for FFS Medi-Cal patients. Drugs not specifically listed remain a Medi-Cal benefit subject to prior authorization from a Medi-Cal consultant. State legislation was enacted in 1990, that enabled DHS to contract with drug manufacturers to obtain rebates for drugs dispensed to FFS outpatient Medi-Cal beneficiaries. This rebate program complements, rather than conflicts with the federal Medicaid rebate law. Because of negotiating state supplemental rebates, DHS often secures rebates in addition to those required under federal law. Rebates over and above those required to be paid to the State under federal law have been possible due to leverage DHS has with manufacturers regarding drug contracting in exchange for adding their drugs to the List.

OTHER STATES' INFORMATION:

Florida Medicaid is the only other state Medicaid program with a broad supplemental rebate program.

FISCAL IMPACT:

There is no fiscal impact if the Medi-Cal drug rebate program sunset date is eliminated. There would, however, be a significant fiscal impact if the drug rebate program were allowed to sunset and DHS could no longer negotiate and collect rebates.

ECONOMIC IMPACT:

There is no economic impact if the Medi-Cal drug rebate program sunset date is eliminated.

LEGAL IMPACT: Unknown.

APPOINTMENTS: None.

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Rail Report Page 75 Bill Number: AB 442

Enrolled Bill Report

Author: Committee on Budget

SUPPORT/OPPOSITION:

Support: None known. Opposition: None known.

ARGUMENTS:

Pro: Elimination of the drug rebate sunset date avoids the necessity of repeatedly seeking

reauthorization every year or two while maintaining the fiscal integrity of this cost-saving

program.

Con: None

SECTION 57

ANALYSIS:

This section would protect federal and state supplemental drug rebates due to the Medi-Cal program when drug manufacturers report changes in Best Price (BP) or Average Manufacturers Price (AMP). The federal Medicaid rebate and Medi-Cal supplemental rebates are based on either BP or AMP. BP is defined in federal law as the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity. AMP is defined in federal law as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts. Manufacturers can, at any time, recalculate these reference prices. By increasing BP or decreasing AMP, the amount of rebate money due to Medi-Cal decreases. Since these changes occur retroactively, it results in Medi-Cal refunding money or giving rebate credit to the manufacturer.

One of the criteria used by Medi-Cal to add or retain drugs on the List is cost. Retroactive reductions in rebate weaken previous Medi-Cal negotiations. This section would protect rebates and the decisions made based on those rebates. The Medi-Cal drug rebate program currently generates significant fiscal savings per year in rebates; projected to be approximately \$1.1 billion TF. Approximately \$280 million of the \$1.1 billion are from supplemental rebates.

LEGISLATIVE HISTORY:

Prior to 1990, DHS did not contract for supplemental drug rebates. Budget Trailer Bill language established the original contracting authority in 1990. Chapter 716, Statutes of 1992 (SB 1063) extended a January 1, 1993, sunset date to January 1, 1999; Chapter 722, Statutes of 1992 (SB 485) revised the sunset date back to January 1, 1997. Chapter 197, Statutes of 1996 (AB 3483) extended the sunset date to January 1, 1999. Chapter 310, Statutes of 1998 (AB 2780) extended the sunset date to January 1, 2000. Chapter 146, Statutes of 1999 (AB 1107) extended the sunset date to January 1, 2001. Chapter 93, Statutes of 2000 (AB 2877) extended the sunset date to January 1, 2003.

Rebate protection language has never been proposed.

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Author: Committee on Budget

PROGRAM BACKGROUND:

The Medi-Cal drug program in DHS maintains the outpatient drug List. This List is used by physicians when prescribing medications for FFS Medi-Cal patients. Drugs not specifically listed remain a Medi-Cal benefit subject to prior authorization from a Medi-Cal consultant. State legislation was enacted in 1990, which enabled DHS to contract with drug manufacturers to obtain rebates for drugs dispensed to FFS outpatient Medi-Cal beneficiaries. This rebate program complements, rather than conflicts with the federal Medicaid rebate law. Because of negotiating state supplemental rebates, DHS often secures rebates in addition to those required under federal law. Rebates over and above those required to be paid to the State under federal law have been possible due to leverage DHS has with manufacturers regarding drug contracting in exchange for adding their drugs to the List.

OTHER STATES' INFORMATION:

Florida Medicaid is the only other state Medicaid program with a broad supplemental rebate program. No state Medicaid program has rebate protection laws or regulations.

FISCAL IMPACT:

It is estimated that approximately \$14 million TF (\$7million GF) would be saved by preventing the recalculation of rebates due to changes in BP and AMP.

FCONOMIC IMPACT: None known.

LEGAL IMPACT: Unknown.

APPOINTMENTS: None.

SUPPORT/OPPOSITION:

Support: None known.

Opposition: Pharmaceutical Research and Manufacturers of America

ARGUMENTS:

Pros: Preventing the recalculation of the rebate due would protect the fiscal integrity of the Medi-Cal

program.

Cons: None

SECTION 58

ANALYSIS:

Existing law provides for specific reimbursement increases to pharmacists. Section 58 would add language to negate the increases and reduce reimbursement to pharmacists in the amount reimbursement was increased. Pharmacy claim reductions for beneficiaries in a nursing facility are exempt, to assure compliance with the Governor's directive to exempt long-term care facilities from any reimbursement rate reductions.

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Author: Committee on Budget

Effective January 1, 2000, the pharmacy reimbursement for each drug claim was increased by \$0.25. Effective July 1, 2002, the pharmacy reimbursement for each claim was to be increased by an additional \$0.15. This section of the trailer bill eliminates the January 1, 2000 increase and rescinds the July 1, 2002 increase.

LEGISLATIVE HISTORY:

SB 651 (Burton, Chapter 190, Statutes of 1999) required that Medi-Cal reimbursement to pharmacies for each prescription claim would be increased by 25 cents on January 1, 2000, and by an additional 15 cents on July 1, 2002. SB 651 was intended to reverse the reduction of 50 cents in pharmacy reimbursement effective January 1, 1995. AB 523 (Vargas, 2002) would chapter out the changes made in this section, resulting in no change in the current reimbursement for pharmacists.

PROGRAM BACKGROUND:

DHS provides reimbursement to pharmacies for medically necessary prescription drugs provided to Medi-Cal beneficiaries. Pharmacies are reimbursed for the ingredient cost of the prescription and a per prescription professional or "dispensing" fee. This professional fee is currently \$4.20 per prescription, including the July 1, 2002 increase.

OTHER STATES' INFORMATION: Not applicable.

FISCAL IMPACT:

The Governor's May Revision includes LTC patients in the pharmacy professional fee reduction, for a total savings of \$23.8 million TF (\$11.9 million GF). The Budget Conference Committee action excluded LTC patients, resulting in a revised savings of \$21.4 million TF (\$10.7 million GF).

Reduction of \$.25 per Rx = \$12,456,000 (LTC patients are excluded from the reductions)

.15 increase not implemented = .8,964,000\$ 21,420,000 (\$10,710,000 GF)

ECONOMIC IMPACT:

This bill would decrease the amount of Medi-Cal reimbursement to pharmacists, thus impacting pharmacies, especially small independent pharmacies with large Medi-Cal clientele.

LEGAL IMPACT: None.

APPOINTMENTS: None.

SUPPORT/OPPOSITION:

Support: None known. Opposition: None known.

Author: Committee on Budget

ARGUMENTS:

Pro: Section 58 will allow DHS to save an estimated \$21.5 million total funds or \$10.7 million general fund by reducing Medi-Cal reimbursement to pharmacists. Due to the current state budget crisis, such a measure becomes necessary. Thus, DHS will be able to contribute to government efforts to minimize the adverse effects of the budget crisis in California.

Con: Section 58 will reduce the Medi-Cal professional fee rate to pharmacists to the pre-January 1, 2000 levels. These levels were already low, compared to other states' Medicaid programs.

SECTIONS 59 & 60

ANALYSIS:

These sections would eliminate the January 1, 2003, sunset provisions of the Medi-Cal drug rebate program (SEC. 55,56,59,60,62,63,65,66,68,69) and would delete sections of law that become operative due to the January 1, 2003, sunset (SEC. 64,67,75,78,79,80). Several sections contain clean-up language changing Health Care Financing Administration to its new title, Centers for Medicare and Medicaid Services (SEC. 56,59,70).

Budget Trailer Bill language established the Medi-Cal drug rebate program in 1990. Since that time several extensions to the sunset date have been enacted. The most recent extension of the Medi-Cal drug rebate program was enacted in AB 2877 (Chapter 93, Statutes of 2000) for two additional years and is now due to sunset January 1, 2003.

Eliminating the sunset date and related sections would enable DHS to continue to operate the drug rebate program as it has since 1990. The sunset of the Medi-Cal drug rebate program would cause the:

- DHS to lose authority to collect \$280 million in rebates greater than the federally-mandated amount;
- Program to revert to a lengthy and burdensome regulatory process for making changes to the Medi-Cal drug formulary.

The elimination of the sunset is consistent with the following provisions of DHS's Strategic Plan: 1) Ensuring fiscal accountability of programs and services; 2) Reforming DHS's administration and program management, including external contracting, into a rational, business-like, and outcome oriented approach.

The Medi-Cal drug rebate program currently generates significant fiscal savings per year in rebates over-and-above the rebates paid to the State under the federal Medicaid drug rebate program. Reauthorization of this program would avoid the loss of these additional drug rebate savings. Without reauthorization, beginning January 1, 2003, current law requires DHS to return to the system in place prior to 1990 in which there was no drug contracting for additional rebates and each addition to the drug formulary required a change in regulations. Neither DHS nor drug manufacturers would like to reinstate the regulatory process as a requirement for drug additions to the Medi-Cal drug formulary.

Author: Committee on Budget

Drug additions through this regulatory process were much slower compared to the current contract negotiation process (18 months average compared to 6 to 9 months). This now obsolete process also resulted in fewer new drug additions (4 to 5 new drug additions per year in 1988 and 1989 compared to 20 to 30 new additions per year from 1996 to 1998), presumably due to cost concerns that are often mitigated through drug rebate contracting.

LEGISLATIVE HISTORY:

Prior to 1990, DHS did not contract for supplemental drug rebates and each addition to the Medi-Cal drug formulary required a change in regulations. Budget Trailer Bill language established the original contracting authority in 1990. Chapter 716, Statutes of 1992 (SB 1063) extended a January 1, 1993, sunset date to January 1, 1999; Chapter 722, Statutes of 1992 (SB 485) revised the sunset date back to January 1, 1997. Chapter 197, Statutes of 1996 (AB 3483) extended the sunset date to January 1, 1999. Chapter 310, Statutes of 1998 (AB 2780) extended the sunset date to January 1, 2000. Chapter 146, Statutes of 1999 (AB 1107) extended the sunset date to January 1, 2001. Chapter 93, Statutes of 2000 (AB 2877) extended the sunset date to January 1, 2003.

PROGRAM BACKGROUND:

The Medi-Cal drug program in DHS maintains the Medi-Cal List of Contract Drugs (List). This outpatient drug List is used by physicians when prescribing medications for FFS Medi-Cal patients. Drugs not specifically listed remain a Medi-Cal benefit subject to prior authorization from a Medi-Cal consultant. State legislation was enacted in 1990, that enabled DHS to contract with drug manufacturers to obtain rebates for drugs dispensed to FFS outpatient Medi-Cal beneficiaries. This rebate program complements, rather than conflicts with the federal Medicaid rebate law. Because of negotiating state supplemental rebates, DHS often secures rebates in addition to those required under federal law. Rebates over and above those required to be paid to the State under federal law have been possible due to leverage DHS has with manufacturers regarding drug contracting in exchange for adding their drugs to the List.

OTHER STATES' INFORMATION:

Florida Medicaid is the only other state Medicaid program with a broad supplemental rebate program.

FISCAL IMPACT:

There is no fiscal impact if the Medi-Cal drug rebate program sunset date is eliminated. There would, however, be a significant fiscal impact if the drug rebate program were allowed to sunset and DHS could no longer negotiate and collect rebates.

ECONOMIC IMPACT:

There is no economic impact if the Medi-Cal drug rebate program sunset date is eliminated.

LEGAL IMPACT: Unknown.

APPOINTMENTS: None.

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Author: Committee on Budget

SUPPORT/OPPOSITION:

Support: None known. Opposition: None known.

ARGUMENTS:

Elimination of the drug rebate sunset date avoids the necessity of repeatedly seeking

reauthorization every year or two while maintaining the fiscal integrity of this cost-saving

program.

Con: None.

SECTION 61

ANALYSIS

This section would close a technical gap that currently exists regarding the suspension or deletion of drugs from the List. This section would also eliminate the January 1, 2003, sunset provisions of the Medi-Cal drug rebate program (see sunset elimination analysis for Sec. 59 and 60).

Currently, the law allows for the suspension or deletion of any drug at the expiration of a contract or when a manufacturer or Medi-Cal terminates a contract. There are many drugs on the List that, for one reason or another, were added without a contract. Since current language only references drugs that currently have a contract or have had a contract in the past, language is needed that deals with drugs that have never had a contract. This language would allow DHS to take appropriate action to suspend or delete a drug from the List under specific circumstances and using the same process, as a contract drug. DHS is currently not targeting any drugs for suspension or deletion that this change in statute would cover.

LEGISLATIVE HISTORY:

Prior to 1990, DHS did not contract for supplemental drug rebates and each addition to the Medi-Cal drug formulary required a change in regulations. Budget Trailer language established the original contracting authority in 1990. Chapter 716, Statutes of 1992 (SB 1063) extended a January 1, 1993, sunset date to January 1, 1999; Chapter 722, Statutes of 1992 (SB 485) revised the sunset date back to January 1, 1997. Chapter 197, Statutes of 1996 (AB 3483) extended the sunset date to January 1, 1999. Chapter 310, Statutes of 1998 (AB 2780) extended the sunset date to January 1, 2000. Chapter 146, Statutes of 1999 (AB 1107) extended the sunset date to January 1, 2001. Chapter 93, Statutes of 2000 (AB 2877) extended the sunset date to January 1, 2003.